

## REMARKS

The Office action mailed June 1, 2006 has been received and reviewed. All claims currently under consideration were rejected. Reconsideration is respectfully requested.

The application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. Basis for the amendments to claim 13 can be found, *inter alia*, in paragraph [0041] of the application as filed. Basis for the amendments to claim 16 can be found, *inter alia*, in paragraph [0043] of the application as filed. Basis for the amendments to claim 19 can be found, *inter alia*, in paragraph [0047] of the application as filed. Basis for the amendments to claim 27 can be found, *inter alia*, in paragraph [0056] of the application as filed. No new matter has been added.

### A. 35 U.S.C. § 112, 2<sup>nd</sup> ¶:

Claims 13 through 30 were rejected under the second paragraph of 35 U.S.C. § 112. Claims 17, 22, 25, and 26 have been canceled, thus obviating the need to respond to the rejection as to them. Applicants have amended other rejected claims, and in view of the amendments, request that the rejections be withdrawn.

Specifically, claims 13, 16, 19, 27, and 29 were rejected for allegedly lacking a nexus between the preamble and end result. These claims have been accordingly amended to clarify the nexus between the preamble and end result.

Claim 18 was rejected for the use of a term lacking antecedent basis. Claim 18 has been amended to clarify the situation.

Claims 28 and 30 were rejected for use of “essentially related” terminology. The claims have been amended to remove the rejected language.

In view of the foregoing, applicants request that these rejections be withdrawn.

### B. 35 U.S.C. § 112, 1<sup>st</sup> ¶:

Claims 13 through 18 and 27-33 were rejected under the first paragraph of 35 U.S.C. § 112 for assertedly lacking enablement. Claims 17, 22, 25, 26, 32, and 33 have been canceled, thus obviating the need to respond to the rejection as to them. Applicants have amended other rejected claims, and in view of the amendments, request that the rejections be withdrawn.

As specifically identified in the Office action, “the specification, [is enabled] for methods employing relative ratios of mitochondrial nucleic acids to chromosomal nucleic acids”. (Office Action, p. 4). Applicants have, accordingly, amended rejected claims 13 through 16, 18 through 21, 23, 24, 27 through 31, to recite, for example, a ratio of mitochondrial nucleic acid to chromosomal nucleic acid, which amendments should overcome the rejection.

Claims 16 through 26 were also rejected under the first paragraph of 35 U.S.C. § 112 for allegedly lacking enablement beyond “HIV-related diseases”.

Claims 17, 22, 25, and 26 have been canceled, thus obviating the need to respond to the rejection as to them.

Applicants have amended rejected claims 16, 18, and 20 to specifically recite HIV-related diseases, and in view of the amendments, request that the rejections against these claims be withdrawn. Similarly, claim 24 recites drugs useful in the treatment of HIV-related diseases, and applicants request that the rejection of this claim also be withdrawn.

With respect to amended claims 19, 21, and 23, applicants traverse the rejection, and assert that the specification does provide sufficient basis for the methods there claimed without requiring undue experimentation. Accordingly, applicants request that this rejection too be withdrawn.

### C. 35 U.S.C. § 102:

Claims 1-3, 8-11, 13, 16, 19, 27, and 29 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tabiti et al. (EP 1 138 783 A2). Claims 1-11, 13-22, 24, and 27-34 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Stuyver et al. (U.S. 20030124512 A1). Claims 17, 22, 32, and 33 have been canceled, thus obviating the need to respond to the rejections as to them. Applicants have amended the other rejected claims, and in view of the amendments, request that the rejections be withdrawn.

The amended claims are novel over Tabiti et al. and Stuyver et al. because neither Tabiti et al. nor Stuyver et al. discloses a method comprising determining the ratio of the amplification rates of at least two nucleic acids. The ratio of the amplification rates is correlated to the ratio of the initial amounts of the at least two nucleic acids. This procedure is, for instance, outlined in paragraph [0068] last four lines of the specification. Tabiti et al. and Stuyver et al. are not

believed to disclose such a determination or correlation, and applicants thus request that the rejections be withdrawn.

**D. 35 U.S.C. § 103:**

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabiti et al. in view of Henegariu et al. "Multiplex PCR: Critical Parameters and Step-by-step Protocol" *BioTechniques*, 23:504-511 (Sept. 1997). As previously identified, applicants have amended the rejected claims, and in view of the amendments, request that the rejections be withdrawn.

Henegariu et al. does not overcome the deficiencies of Tabiti et al. and Stuyver et al. (*i.e.*, it does not disclose determining a ratio of the amplification rates of the at least two nucleic acids of interest), thus the obviousness rejection should be overcome.

**E. Obviousness-type Double Patenting:**

Claims 1 and 13-34 are rejected under the doctrine of obviousness-type double patenting over claim 11 of U.S. Patent 6,967,016 to van Gemen et al. Claims 2-8 are rejected under the doctrine of obviousness-type double patenting over claim 11 of U.S. Patent 6,967,016 to van Gemen et al. in view of van Deursen et al. Claims 17, 22, 25, 26, 32, and 33 have been canceled, thus obviating the need to respond to the rejection as to them. Applicants respectfully traverse the remainder of the rejections.

Applicants do not quite understand the obviousness-type double patenting rejections. As understood by applicants, according to the Examiner, the method set forth in claim 11 of US 6,976,016 allegedly represents a species of the genus method set forth in claim 1 of the instant application. Applicants are, however, of the opinion that US Patent 6,976,016 to van Gemen et al. and the current application address different issues and would not render one another obvious, and thus the doctrine of obviousness-type double patenting should not apply.

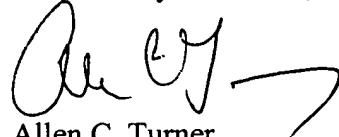
The instant application discloses (and claims) the insight that the ratio of the amplification rates of two nucleic acids is indicative of the ratio of the initial amounts of the two nucleic acids. Hence, the current application provides a particular way of determining the initial amounts of nucleic acids.

In contrast, claim 11 of US Patent 6,976,016 to van Gemen et al. is not restricted to any

particular way of determining the relative ratio of the amounts of nucleic acid. Methods other than the methods disclosed in the current application are suitable for US Patent 6,976,016 to van Gemen et al. as well. Accordingly, the doctrine should not apply.

The application should now be in condition for allowance. If questions remain after consideration of the foregoing, however, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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